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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/720,265 | 11/25/2003 | Vincent Fischetti | | 4611 |

7590 06/26/2006

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EXAMINER

KIM, TAEYOON

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|----------------------------------|--|
| Office Action Summary | Application No. 10/720,265 | Applicant(s) FISCHETTI ET AL. | |
| | Examiner Taeyoon Kim | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/25/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82-102 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 96-98 is/are allowed.
- 6) ☒ Claim(s) 82-95 and 99-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/25/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 82-102 are pending.

Claim Objections

1. Claim 84 is objected to because of the following informalities: The claim sentence is not finished with a period at the end of the sentence. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

Art Unit: 1651

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 82, 84, 86-93 and 100-102 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 13-23, 25 and 26 of U.S. Patent No. 5,997,862. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parenteral compositions comprising at least one lytic enzyme (lysin) and a parenteral carrier. The current application claims a list of specific lytic enzymes for a specific bacteria (genus), whereas '862 claims a lysin enzyme from group C streptococcal bacteria (species). Thus, the claims of the current application are anticipated by the claims of '862. A term "parenteral" is defined as "introduced otherwise than by way other the intestines" in Merriam-Webster OnLine dictionary (<http://www.m-w.com/dictionary/parenteral>). Therefore, delivery to mouth, throat or nasal passage

using a carrier such as an aerosol or a spray falls within broadest reasonable interpretation of a parenteral delivery.

3. Claims 82, 84, 86-95 and 100-103 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-10, 13-25, 27 and 28 of U.S. Patent No. 6,017,528. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parenteral compositions comprising at least one lytic enzyme (lysin) and a parenteral carrier. The current application claims a list of specific lytic enzymes for a specific bacteria (genus), whereas '528 claims a lysin enzyme from group C streptococcal bacteria (species). Thus, the claims of the current application are anticipated by the claims of '528. A parenteral delivery is one that enters the body in a way other than intestines. Therefore, delivery to mouth, throat or nasal passage using a carrier such as an aerosol or a spray falls within broadest reasonable interpretation of a parenteral delivery.

4. Claims 82, 84, 86-95, and 99 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-33, 35, 39-41 and 45 of U.S. Patent No. 6,056,955. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parenteral compositions comprising at least one lytic (lysin) enzyme and a parenteral carrier. The current application claims a list of specific lytic enzymes for a

Art Unit: 1651

specific bacteria (genus), whereas '955 claims a lysin enzyme from group C streptococcal bacteria (species). Thus, the claims of the current application are anticipated by the claims of '955. A parenteral delivery is one that enters the body in a way other than intestines. Therefore, dermatological delivery falls within broadest reasonable interpretation of a parenteral delivery.

5. Claims 82, 83, 85 and 100-102 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,277,399. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parenteral compositions comprising at least one lytic enzyme and a parenteral carrier. The current application claims that the lytic enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holin lytic enzymes and combinations of thereof, whereas '399 claims a lytic enzyme. Since a lytic enzyme claimed in '399 is in the list of lytic enzymes claimed in the current application, the claims of the current application are anticipated by the claims of '399. A parenteral delivery is one that enters the body in a way other than intestines. Therefore, a topical patch or a bandage falls within broadest reasonable interpretation of a parenteral delivery.

6. Claims 82, 84 and 100-102 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,399,098. Although the conflicting claims are not identical, they are not patentably

distinct from each other because both sets of claims are directed to parenteral compositions comprising at least one lytic enzyme and a parenteral carrier. The claims differ in the limitation of an enzyme used in the therapeutic agent. The current application claims that the lytic enzyme(s) specific for a specific bacteria is selected from a group of lytic, shuffled lytic, chimeric lytic, holin lytic enzymes and combinations of thereof, whereas '098 claims a lytic enzyme specific for *Streptococcus mutans*. The claims to the lytic enzymes in the current application are anticipated by the claims to a specific lytic enzyme for *Streptococcus mutans* in '098. A parenteral delivery is one that enters the body in a way other than intestines. Therefore, a lozenge falls within broadest reasonable interpretation of a parenteral delivery.

7. Claims 82, 83, 85, 93 and 100-102 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,406,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parenteral compositions comprising at least one lytic enzyme and a parenteral carrier. The current application claims that the lytic enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holin lytic enzymes and combinations of thereof, whereas '692 claims a lytic enzyme. Since a lytic enzyme claimed in '692 is a part of the lytic enzymes claimed in the current application, the claims of the current application are anticipated by the claims of '692. A parenteral delivery is one that enters the body in a way other

than intestines. Therefore, an isotonic eye drop solution falls within broadest reasonable interpretation of a parenteral delivery.

8. Claims 82, 84, 86-95 and 100-102 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9 and 10 of U.S. Patent No. 6,423,299. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parenteral compositions comprising at least one lytic enzyme and a parenteral carrier. The current application claims that the lytic enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holin lytic enzymes and combinations of thereof, whereas '299 claims a lytic enzyme. Since a lytic enzyme claimed in '299 is a part of the lytic enzymes claimed in the current application, the claims of the current application are anticipated by the claims of '299. A parenteral delivery is one that enters the body in a way other than intestines. Therefore, an aerosol composition falls within broadest reasonable interpretation of a parenteral delivery.

9. Claims 82, 83-85, 93 and 100-102 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,432,444. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parenteral compositions comprising at least one lytic enzyme and a parenteral carrier. The current application claims that the lytic enzyme(s) is selected from lytic, shuffled

Art Unit: 1651

lytic, chimeric lytic, holin lytic enzymes and combinations of thereof, whereas '444 claims a lytic enzyme. Since a lytic enzyme claimed in '444 is a part of the lytic enzymes claimed in the current application, the claims of the current application are anticipated by the claims of '444. A parenteral delivery is one that enters the body in a way other than intestines. Therefore, a bandage falls within broadest reasonable interpretation of a parenteral delivery.

10. Claims 82, 84, 86-95 and 100-102 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 46-56, 58 and 59 of copending Application No. 10/720266. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parenteral compositions comprising at least one lytic enzyme and a parenteral carrier. The current application claims that the lytic enzyme(s) specific for a specific bacteria is selected from a group of lytic, shuffled lytic, chimeric lytic, holin lytic enzymes and combinations of thereof, whereas Application No. '266 claims a lytic enzyme specific for *Streptococcus Group A* coded by *Streptococcus Group A* specific bacteriophage. The claims to the lytic enzymes in the current application are anticipated by the claims to a specific lytic enzyme for *Streptococcus Group A* in '266. A parenteral delivery is one that enters the body in a way other than intestines. Therefore, a lozenge falls within broadest reasonable interpretation of a parenteral delivery.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

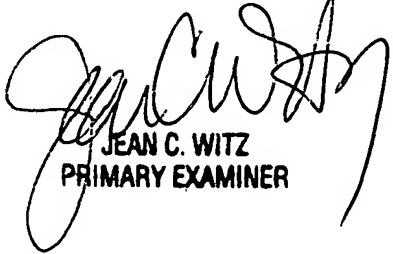
11. Claims 82-102 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
Patent Examiner
Art Unit 1651


JEAN C. WITZ
PRIMARY EXAMINER